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TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P.
1300 EAST NINTH STREET, SUITE 1700
CLEVEVLAND, OH 44114

EXAMINER	
TOWA, RENE T	

ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)
	10/813,986	MUSCHLER, GEORGE F.
	Examiner	Art Unit
	Rene Towa	3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on ____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-19,37,39-51 and 53-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-19,37,39-51 and 53-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03/09/06*.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is responsive to an amendment filed March 17, 2006. Claims 1-7, 9-19, 37, 39-51 and 53-71 are pending. Claims 1, 16, 37, 40, 43-44, 46, and 53 are amended. Claims 8, 20-36 and 52 are cancelled. Claims 55-71 are added.

Claim Objections

2. The objections are withdrawn due to amendments.

Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 55-56, 58, 61-62 and 64-71 are rejected under 35 U.S.C. 102(b) as being anticipated by Perez et al. (US Patent No. 6,132,448).

In regards to claim 55, Perez et al. disclose a minimally invasive apparatus 10 capable of harvesting bone marrow cells, blood, and bone fragments, said apparatus 10 comprising:

a rigid cannula 11 having a proximal end and a distal end with an opening 12, said distal end including a cutting tip that is movable axially and radially to cut and disrupt bone tissue while preserving necessary viability among harvested marrow cells, said cannula 11 further including an inner surface 14 defining an internal passage (23, 29) that extends from said opening 12 toward said proximal end; and

means capable of applying suction to said internal passage (23, 29) in said cannula 11 capable of drawing bone marrow cells, blood, and bone fragments disrupted

from the bone tissue by said cutting tip into said internal passage (23, 29) capable of collection (see figs. 1-2 & 7-8; column 4/lines 1-12);

means 18 capable of controllably supplying irrigation fluid to said internal passage 29 in said cannula 11 (see figs. 1-2; column 2/lines 47-53);

means 18 capable of controllably injecting an anticoagulant fluid into the harvested bone marrow cells, blood, and bone fragments during collection (see figs. 1-2; column 2/lines 47-53).

In regards to claim 56, Perez et al. disclose a minimally invasive apparatus 10 further comprising control means L capable of controlling said means capable of applying suction (see column 4/lines 1-12).

In regards to claim 58, Perez et al. disclose a minimally invasive apparatus 10 wherein said cannula 11 further includes a plurality of nozzles 13 adjacent said distal end capable of introducing anticoagulant fluid into harvested bone marrow cells, blood, and bone fragments immediately following their harvest (see fig. 6; column 2/lines 30-38; column 3/lines 47-54).

In regards to claim 61, Perez et al. disclose a minimally invasive apparatus 10 further comprising a rotatable shaft 27 disposed co-axially within said internal passage (23, 29) in said cannula 11, said shaft 27 having a distal end with a cutting bit 24 capable of cutting and disrupting bone tissue while preserving necessary viability among harvested marrow cells, said cutting bit 24 projecting through said opening 12 in said cannula 11 (see figs. 2 & 7; column 2/lines 56-67).

In regards to claim 62, Perez et al. disclose a minimally invasive apparatus 10 further comprising means capable of rotating said shaft 27 and said cutting bit 24 (see column 3/lines 16-19, 31-35).

In regards to claim 64, Perez et al. disclose a minimally invasive apparatus 10 wherein said cannula 11 includes a radially extending end wall 34 that closes off a portion of said opening 12 at said distal end of said cannula 11, said end wall 34 having an axially extending passage 25 through which said shaft 27 projects (see fig. 5).

In regards to claim 65, Perez et al. disclose a minimally invasive apparatus 10 wherein said cannula 11 includes a plurality of circumferentially spaced radially extending apertures 13 through which bone marrow cells, blood, and bone fragments disrupted from the bone tissue are capable of being aspirated by said means capable of applying suction (see fig. 6; column 2/lines 30-38; column 3/lines 47-54).

In regards to claim 66, Perez et al. disclose a minimally invasive apparatus 10 wherein said cannula 11 includes a plurality of circumferentially spaced radially extending apertures 13 through which bone marrow cells, blood, and bone fragments disrupted from the bone tissue are capable of being aspirated by said means capable of applying suction (see fig. 6; column 2/lines 30-38; column 3/lines 47-54).

In regards to claim 67, Perez et al. disclose a minimally invasive apparatus 10 wherein said opening 12 at said distal end of said cannula 11 extends in the radial direction through said inner surface 14 of said cannula 11 (see figs. 1-2).

In regards to claim 68, Perez et al. disclose a minimally invasive apparatus 10 wherein said distal end of said cannula 11 includes a plurality of third nozzles 13

adjacent said radial opening 12 capable of introducing an anticoagulant fluid into harvested bone marrow cells, blood, and bone fragments (see fig. 6; column 2/lines 30-38; column 3/lines 47-54).

In regards to claim 69, Perez et al. disclose a minimally invasive apparatus 10 further comprising a rotatable shaft 27 disposed coaxially with said internal passage (23, 29) in said cannula 11, said shaft 27 having a distal end with a cutting bit 24 capable of cutting and disrupting bone tissue while preserving necessary viability among harvested marrow cells, said cutting bit 24 being disposed within said radial opening 12 in said cannula 11 (see figs. 2 & 7; column 2/lines 56-67).

In regards to claim 70, Perez et al. disclose a minimally invasive apparatus 10 wherein said cannula 11 includes a radially extending wall that closes off a portion of said internal passage 29 at said distal end of said cannula 11, said end wall 34 having an axially extending passage 25 through which said shaft 27 projects (see fig. 5).

In regards to claim 71, Perez et al. disclose a minimally invasive apparatus 10 wherein said cannula 11 includes a plurality of circumferentially spaced radially extending apertures 13 through which bone marrow cells, blood, and bone fragments disrupted from the bone tissue are capable of being aspirated by said means capable of applying suction (see fig. 6; column 2/lines 30-38; column 3/lines 47-54).

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-3, 5-6, 8-10, 12-20, 22-24, 26-27, 29-36 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perez et al. (US Patent No. 6,132,448) in view of Huitema et al. (US Patent No. 6,083,237).

In regards to claim 1, Perez et al. disclose a minimally invasive apparatus 10 capable of harvesting bone marrow cells, blood, and bone fragments, said apparatus 10 comprising:

a rigid cannula 11 having a proximal end and a distal end with an opening 12, said distal end including a cutting tip that is movable axially and radially to cut and disrupt bone tissue while preserving necessary viability among harvested marrow cells, said cannula 11 further including an inner surface 14 defining an internal passage (23, 29) that extends from said opening 12 toward said proximal end; and

means capable of applying suction to said internal passage (23, 29) in said cannula 11 capable of drawing bone marrow cells, blood, and bone fragments disrupted from the bone tissue by said cutting tip into said internal passage (23, 29) capable of collection (see figs. 1-2 & 7-8; column 4/lines 1-12).

In regards to claim 2, Perez et al. disclose a minimally invasive apparatus 10 further comprising control means L capable of controlling said means capable of applying suction (see column 4/lines 1-12).

In regards to claim 3, Perez et al. disclose a minimally invasive apparatus 10 further comprising means 18 capable of controllably supplying irrigation fluid to said internal passage 29 in said cannula 11 (see figs. 1-2; column 2/lines 47-53).

In regards to claim 5, Perez et al. disclose a minimally invasive apparatus 10 further comprising means 18 capable of controllably injecting an anticoagulant fluid into the harvested bone marrow cells, blood, and bone fragments during collection (see figs. 1-2; column 2/lines 47-53).

In regards to claim 6, Perez et al. disclose a minimally invasive apparatus 10 wherein said cannula 11 further includes a plurality of nozzles 13 adjacent said distal end capable of introducing anticoagulant fluid into harvested bone marrow cells, blood, and bone fragments immediately following their harvest (see fig. 6; column 2/lines 30-38; column 3/lines 47-54).

In regards to claim 9, Perez et al. disclose a minimally invasive apparatus 10 further comprising a rotatable shaft 27 disposed co-axially within said internal passage (23, 29) in said cannula 11, said shaft 27 having a distal end with a cutting bit 24 capable of cutting and disrupting bone tissue while preserving necessary viability among harvested marrow cells, said cutting bit 24 projecting through said opening 12 in said cannula 11 (see figs. 2 & 7; column 2/lines 56-67).

In regards to claim 10, Perez et al. disclose a minimally invasive apparatus 10 further comprising means capable of rotating said shaft 27 and said cutting bit 24 (see column 3/lines 16-19, 31-35).

In regards to claim 12, Perez et al. disclose a minimally invasive apparatus 10 wherein said cannula 11 includes a radially extending end wall 34 that closes off a portion of said opening 12 at said distal end of said cannula 11, said end wall 34 having an axially extending passage 25 through which said shaft 27 projects (see fig. 5).

In regards to claim 13, Perez et al. disclose a minimally invasive apparatus 10 wherein said cannula 11 includes a plurality of circumferentially spaced radially extending apertures 13 through which bone marrow cells, blood, and bone fragments disrupted from the bone tissue are capable of being aspirated by said means capable of applying suction (see fig. 6; column 2/lines 30-38; column 3/lines 47-54).

In regards to claim 14, Perez et al. disclose a minimally invasive apparatus 10 wherein said cannula 11 includes a plurality of circumferentially spaced radially extending apertures 13 through which bone marrow cells, blood, and bone fragments disrupted from the bone tissue are capable of being aspirated by said means capable of applying suction (see fig. 6; column 2/lines 30-38; column 3/lines 47-54).

In regards to claim 15, Perez et al. disclose a minimally invasive apparatus 10 wherein said opening 12 at said distal end of said cannula 11 extends in the radial direction through said inner surface 14 of said cannula 11 (see figs. 1-2).

In regards to claim 16, Perez et al. disclose a minimally invasive apparatus 10 wherein said distal end of said cannula 11 includes a plurality of third nozzles 13 adjacent said radial opening 12 capable of introducing an anticoagulant fluid into harvested bone marrow cells, blood, and bone fragments (see fig. 6; column 2/lines 30-38; column 3/lines 47-54).

In regards to claim 17, Perez et al. disclose a minimally invasive apparatus 10 further comprising a rotatable shaft 27 disposed coaxially with said internal passage (23, 29) in said cannula 11, said shaft 27 having a distal end with a cutting bit 24 capable of cutting and disrupting bone tissue while preserving necessary viability

among harvested marrow cells, said cutting bit 24 being disposed within said radial opening 12 in said cannula 11 (see figs. 2 & 7; column 2/lines 56-67).

In regards to claim 18, Perez et al. disclose a minimally invasive apparatus 10 wherein said cannula 11 includes a radially extending wall that closes off a portion of said internal passage 29 at said distal end of said cannula 11, said end wall 34 having an axially extending passage 25 through which said shaft 27 projects (see fig. 5).

In regards to claim 19, Perez et al. disclose a minimally invasive apparatus 10 wherein said cannula 11 includes a plurality of circumferentially spaced radially extending apertures 13 through which bone marrow cells, blood, and bone fragments disrupted from the bone tissue are capable of being aspirated by said means capable of applying suction (see fig. 6; column 2/lines 30-38; column 3/lines 47-54).

In regards to claim 20, Perez et al. disclose a minimally invasive apparatus 10 capable of harvesting bone marrow cells, blood, and bone fragments, said apparatus 10 comprising:

a rotatable shaft 27 having a distal end, said distal end including a cutting bit 24 capable of cutting and disrupting bone tissue while preserving necessary viability among harvested marrow cells;

means capable of rotating said shaft 27;

a rigid cannula 11 disposed co-axially about at least a portion of said shaft 27, said cannula 11 having a distal end with an opening 12 through which said cutting bit 24 extends, said cannula 11 further having an inner surface 14 defining an internal

passage (23, 29) that extends from said opening 12 toward a proximal end of said cannula 11; and

means capable of applying suction to said internal passage 23 in said cannula 11 capable of drawing bone marrow cells, blood, and bone fragments disrupted from the bone tissue by said cutting bit 24 into said internal passage 23 capable of collection (see figs. 1-2 & 7-8; column 2/lines 56-67; column 3/lines 16-19, 31-35; column 4/lines 1-12).

In regards to claim 22, Perez et al. disclose a minimally invasive apparatus 10 further comprising control means capable of controlling said means capable of applying suction (see column 4/lines 1-12).

In regards to claim 23, Perez et al. disclose a minimally invasive apparatus 10 further comprising means 18 capable of controllably supplying irrigation fluid to said distal end of said shaft 27 (see figs. 1-2; column 2/lines 47-53).

In regards to claim 24, Perez et al. disclose a minimally invasive apparatus 10 further comprising means 18 capable of controllably supplying irrigation fluid into said internal passage 29 in said cannula 11 (see figs. 1-2; column 2/lines 47-53).

In regards to claim 26, Perez et al. disclose a minimally invasive apparatus 10 further comprising means 18 capable of controllably injecting an anticoagulant fluid into the harvested bone marrow cells, blood, and bone fragments during collection (see figs. 1-2; column 2/lines 47-53).

In regards to claim 27, Perez et al. disclose a minimally invasive apparatus 10 wherein said cannula 11 further includes a plurality of nozzles 13 adjacent said distal

end capable of introducing anticoagulant fluid into harvested bone marrow cells, blood, and bone fragments immediately following their harvest (see fig. 6; column 2/lines 30-38; column 3/lines 47-54).

In regards to claim 29, Perez et al. disclose a minimally invasive apparatus 10 further comprising a sheath 16 disposed coaxially about a portion of said cannula 11 capable of providing and maintaining a single percutaneous puncture site (see fig. 2).

In regards to claim 30, Perez et al. disclose a minimally invasive apparatus 10 wherein said cannula 11 includes a plurality of circumferentially spaced radially extending apertures 13 through which bone marrow cells, blood, and bone fragments disrupted from the bone tissue are aspirated by said means capable of applying suction (see fig. 6; column 2/lines 30-38; column 3/lines 47-54).

In regards to claim 31, Perez et al. disclose a minimally invasive apparatus 10 wherein said cannula 11 includes a radially extending end wall 34 that closes a portion of said opening 12 at said distal end of said cannula 11, said end wall 34 having an axially extending passage 25 through which said shaft 27 projects (see fig. 5).

In regards to claim 32, Perez et al. disclose a minimally invasive apparatus 10 wherein said distal end of said cannula 11 includes a cutting tip that is movable axially and radially to cut and disrupt bone tissue while preserving necessary viability among harvested marrow cells (see figs. 1-2).

In regards to claim 33, Perez et al. disclose a minimally invasive apparatus 10 wherein said opening 12 at said distal end of said cannula 11 extends in the radial direction through said inner surface 14 of said cannula 11 (see figs. 1-2).

In regards to claim 34, Perez et al. disclose a minimally invasive apparatus 10 wherein said distal end of said cannula 11 includes a plurality of third nozzles 13 adjacent said radial opening 12 capable of introducing an anticoagulant fluid into harvested bone marrow cells, blood, and bone fragments (see fig. 6; column 2/lines 30-38; column 3/lines 47-54).

In regards to claim 35, Perez et al. disclose a minimally invasive apparatus 10 wherein said cannula 11 includes a radially extending wall that closes off a portion of said internal passage 29 at said distal end of said cannula 11, said end wall 34 having an axially extending passage 25 through which said shaft 27 projects (see fig. 5).

In regards to claim 36, Perez et al. disclose a minimally invasive apparatus 10 wherein said cannula 11 includes a plurality of circumferentially spaced radially extending apertures 13 through which bone marrow cells, blood, and bone fragments disrupted from the bone tissue are aspirated by said means capable of applying suction (see fig. 6; column 2/lines 30-38; column 3/lines 47-54).

Perez et al. disclose an apparatus, as described above, that teaches all the limitations of the claim except that Perez et al. do not disclose a sheath disposed co-axially about a portion of the cannula. However, Huitema et al. disclose an apparatus comprising a sheath disposed co-axially about a portion of the cannula (see figs. 8-9). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an apparatus similar to that of Perez et al. with a sheath similar to that of Huitema et al. in order to maintain access to a percutaneous site (see Huitema et al., see fig. 9).

7. Claims 1-5 & 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US Patent No. 5,575,293) in view of Huitema et al. (US Patent No. 6,083,237).

In regards to claim 1, Miller et al. disclose a minimally invasive apparatus 202 capable of harvesting bone marrow cells, blood, and bone fragments, said apparatus 202 comprising:

a rigid cannula 204 having a proximal end and a distal end with an opening, said distal end including a cutting tip 206 that is movable axially and radially to cut and disrupt bone tissue while preserving necessary viability among harvested marrow cells, said cannula 204 further including an inner surface defining an internal passage that extends from said opening toward said proximal end; and

means capable of applying suction 216 to said internal passage in said cannula 204 capable of drawing bone marrow cells, blood, and bone fragments disrupted from the bone tissue by said cutting tip 206 into said internal passage for collection (see fig. 5; column 7/lines 31-46).

In regards to claim 2, Miller et al. disclose a minimally invasive apparatus 202 further comprising control means 262 capable of controlling said means for applying suction 216 (see fig. 5; column 7/lines 31-46).

In regards to claim 3, Miller et al. disclose a minimally invasive apparatus 202 further comprising means 208 capable of controllably supplying irrigation fluid into said internal passage in said cannula 204 (see fig. 5).

In regards to claim 4, Miller et al. disclose a minimally invasive apparatus 202 wherein said means 208 capable of controllably supplying irrigation fluid is operatively coupled to control means 250 capable of controlling said means for applying suction in order that irrigation fluid flow and suction can be oscillated so as not to coincide (see fig. 5).

In regards to claim 5, Miller et al. disclose a minimally invasive apparatus 202 further comprising means 208 capable of controllably injecting an anticoagulant fluid into the harvested bone marrow cells, blood, and bone fragments during collection (see fig. 5).

In regards to claim 7, Miller et al. disclose a minimally invasive apparatus 202 further comprising a collection chamber (10, 110) in fluid communication with said internal passage capable of receiving and collecting the harvested bone marrow cells, blood, and bone fragments (see fig. 5).

Miller et al. disclose an apparatus, as described above, that teaches all the limitations of the claim except that Miller et al. do not disclose a sheath disposed co-axially about a portion of the cannula. However, Huitema et al. disclose an apparatus comprising a sheath disposed co-axially about a portion of the cannula (see figs. 8-9). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an apparatus similar to that of Miller et al. with a sheath similar to that of Huitema et al. in order to maintain access to a percutaneous site (see Huitema et al., see fig. 9).

8. Claims 46, 51 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cervi (US Patent Application No. 2002/0042581) in view of Huitema et al. (US Patent No. 6,083,237).

In regards to claim 46, Cervi discloses a minimally invasive method capable of harvesting bone marrow cells, blood, and bone fragments, said method comprising the steps of:

(a) providing an apparatus having a rotatable shaft 17 with a distal end for disrupting bone tissue, the apparatus further including means 27 for rotating the shaft 17 and a cannula 3 encircling the shaft 17 to define an annular passage 1;

(b) inserting the distal end of the shaft 17 through a puncture site, through the cortex of a bone, and into the intramedullary canal of the bone;

(c) rotating the shaft 17 to cause the cutting bit to rotate and disrupt the cancellous bone in the intramedullary canal;

(d) applying suction to the annular passage 1 which draws bone marrow cells, blood, and bone fragments disrupted from the cancellous bone into the annular passage 1 for collection;

(e) manually moving the distal end of the shaft 17 to different locations in the cancellous bone and disrupting additional bone tissue with the apparatus remaining in the same puncture site; and

(f) repeating steps (c) and (d) to further collect bone marrow cells, blood, and bone fragments.

(See fig. 4B; par 0044, at lines 3-12; par 0050, at lines 1-3; par 0058, at lines 1-6; par 0062; par 0064, at lines 1-8, 12-13; par 0065; par 0066, at lines 1-7; par 0067, at lines 1-6).

In regards to claim 51, Cervi discloses a minimally invasive method further comprising the steps of:

providing a collection reservoir 1 for collecting the harvested bone marrow cells, blood, and bone fragments; and

fluidly connecting the passage in the cannula 3 with the collection reservoir 1 (see par 0044, at lines 10-12).

In regards to claim 53, Cervi discloses a minimally invasive method further comprising the steps of:

(a) manually moving the distal end of the cannula in both axial and radial directions within the intramedullary canal to cut and disrupt the bone tissue;

(b) manually moving the distal end of the cannula to different locations in the cancellous bone and disrupting additional bone tissue with the apparatus remaining in the same puncture site; and (c) repeating steps (d) and (e) to further collect bone marrow cells, blood, and bone fragments (see par 0065; par 0066, at lines 1-7; par 0067).

Cervi discloses a method, as described above, that teaches all the limitations of the claim except that Cervi does not disclose a sheath disposed co-axially about a portion of the cannula. However, Huitema et al. disclose a method wherein a sheath 31 is disposed co-axially about a portion of the cannula (see figs. 8-9). It would have been

obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Cervi with a sheath similar to that of Huitema et al. in order to maintain access to a percutaneous site (see Huitema et al., see fig. 9).

9. Claims 46-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shapira (US Patent No. 5,913,859) in view of Huitema et al. (US Patent No. 6,083,237).

In regards to claim 46, Shapira discloses a minimally invasive method capable of harvesting bone marrow cells, blood, and bone fragments, said method comprising the steps of:

(a) providing an apparatus 10 having a rotatable shaft 29 with a distal end for disrupting bone tissue, the apparatus 10 further including means for rotating the shaft 29 and a cannula 17 encircling the shaft 29 to define an annular passage 26;

(b) inserting the distal end of the shaft 29 through a puncture site, through the cortex of a bone 13, and into the intramedullary canal of the bone 13;

(c) rotating the shaft 29 to cause the cutting bit 38 to rotate and disrupt the cancellous bone 13 in the intramedullary canal 13;

(d) applying suction to the annular passage 26 which draws bone marrow cells, blood, and bone fragments disrupted from the cancellous bone into the annular passage 26 for collection;

(e) manually moving the distal end of the shaft 29 to different locations in the cancellous bone and disrupting additional bone tissue with the apparatus 10 remaining in the same puncture site; and

(f) repeating steps (c) and (d) to further collect bone marrow cells, blood, and bone fragments.

(See fig. 2; column 3/lines 61-67; column 4/lines 1-12, 45-49; column 6/lines 43-46, 50-56, 60-65; column 7/lines 5-7, 16-19; column 8/lines 38-56).

In regards to claim 47, Shapira discloses a minimally invasive method further comprising the step of supplying irrigation fluid to the distal end of the shaft 29 to minimize thermal or mechanical trauma to the harvested cells and to help carry the harvested bone marrow cells, blood, and bone fragments into the passage 26 (see fig. 2; column 6/lines 60-65).

In regards to claim 48, Shapira discloses a minimally invasive method further comprising the step of supplying an anticoagulant fluid into the harvested bone marrow cells, blood, and bone fragments to inhibit clot formation (see column 8/lines 38-56).

In regards to claim 49, Shapira discloses a minimally invasive method further comprising the step of oscillating the supply of irrigation fluid and the supply of anticoagulant fluid (see fig. 2).

In regards to claim 50, Shapira discloses a minimally invasive method further comprising the step of supplying the anticoagulant fluid at a location adjacent the distal end of the cannula 17 (see column 8/lines 51-56).

In regards to claim 51, Shapira discloses a minimally invasive method further comprising the steps of:

providing a collection reservoir 56 for collecting the harvested bone marrow cells, blood, and bone fragments; and

fluidly connecting the passage in the cannula 17 with the collection reservoir 56 (see figs. 1-2).

Shapira discloses a method, as described above, that teaches all the limitations of the claim except that Shapira does not disclose a sheath disposed co-axially about a portion of the cannula. However, Huitema et al. disclose a method wherein a sheath 31 is disposed co-axially about a portion of the cannula (see figs. 8-9). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Shapira with a sheath similar to that of Huitema et al. in order to maintain access to a percutaneous site (see Huitema et al., see fig. 9).

10. Claims 11, 21, 25, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perez et al. ('448) in view of Huitema et al. ('237) further in view of Miller et al. ('293).

In regards to claims 11, 21 & 25, Perez et al. as modified by Huitema et al. disclose a minimally invasive apparatus, as described above, that teaches all the limitations of the claim except Perez et al. as modified by Huitema et al. do not explicitly teach control means. However, Miller et al. disclose an apparatus 202 comprising control means 250 capable of operatively controlling irrigation fluid flow and suction (see fig. 5). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an apparatus similar to that of Perez et al. as modified by Huitema et al. with control means similar to that of Miller et al. in order to regulate the apparatus usage (i.e. using an on/off switch).

In regards to claim 28, Perez et al. as modified by Huitema et al. disclose a minimally invasive apparatus, as described above, that teaches all the limitations of the claim except Perez et al. as modified by Huitema et al. do not explicitly teach a collection chamber. However, Miller et al. disclose an apparatus 202 comprising a collection chamber (10, 110) (see fig. 5). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an apparatus similar to that of Perez et al. as modified by Huitema et al. with a collection chamber similar to that of Miller et al. in order to collect the disrupted tissue.

11. Claims 37, 39, 40-42 & 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sramek et al. (US Patent Application No. 2003/0055373) in view of Shapira (US Patent No. 5,913,859).

In regards to claim 37, Sramek et al. disclose a minimally invasive method for harvesting bone marrow cells, blood, and bone fragments, said method comprising the steps of:

(a) providing a cannula 110 having a proximal end 112 and a distal end 111 with an opening 120, the distal end 111 including a cutting tip capable of disrupting bone tissue while preserving necessary viability among harvested marrow cells, the cannula 110 further including an inner surface defining an internal passage that extends from the opening toward the proximal end 112;

(b) inserting the distal end 111 of the cannula 110 through a puncture site, through the cortex of a bone, and into the intramedullary canal of the bone;

(c) applying suction to the internal passage which draws bone marrow cells, blood, and bone fragments disrupted from the cancellous bone into the internal passage for collection;

(d) manually moving the distal end 111 of the cannula 110 in both axial and radial directions within the intramedullary canal to cut and disrupt the bone tissue;

(e) manually moving the distal end 111 of the cannula 110 to different locations in the cancellous bone and disrupting additional bone tissue with the apparatus remaining in the same puncture site; and

(f) repeating steps (d) and (e) to further collect bone marrow cells, blood, and bone fragments.

(See figs. 1A-E; par 0071, at lines 2-8; par 0072, at lines 6-11; par 0073, at lines 1-3, 7-12, 16-21; par 0074, at lines 3-9; par 0075, at lines 11-14; par 0077, at lines 1-9; par 0080, at lines 1-13; par 0081, at lines 1-11; par 0082, at lines 1-3).

In regards to claim 39, Sramek et al. disclose a minimally invasive method further comprising the step of supplying an anticoagulant fluid into the harvested bone marrow cells, blood, and bone fragments to inhibit clot formation (see par 0046, at lines 20-24).

In regards to claim 42, Sramek et al. disclose a minimally invasive method further comprising the steps of:

providing a collection reservoir 160 for collecting the harvested bone marrow cells, blood, and bone fragments; and

fluidly connecting the internal passage in the cannula 110 with the collection reservoir 160 (see fig. 1E; par 0080, at lines 1-13).

In regards to claim 44, Sramek et al. disclose a minimally invasive method further comprising the steps of:

providing a rotatable shaft 125 disposed co-axially within the internal passage in the cannula 110, the shaft having distal end 111 with a cutting bit 135 that projects through the opening 120 in the cannula 110; and

rotating the shaft 125 and the cutting bit 135 to cut and disrupt bone tissue in the intramedullary canal while preserving necessary viability among harvested marrow cells (see fig. 1E).

In regards to claims 37, Sramek et al. disclose a method, as described above, that teaches all the limitations of the claim except Sramek et al. do not disclose an irrigation fluid supply step. However, Shapira discloses a minimally invasive method comprising the step of supplying irrigation fluid to the distal end of the cannula (see column 6/lines 60-65). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Sramek et al. with a method step similar to that of Shapira in order to cool the extraction site and add liquid to the extracted fluids and solids to facilitate removal by suction (see Shapira, column 6/lines 60-65).

In regards to claims 40-41, Sramek et al. disclose a method, as described above, that teaches all the limitations of the claim except Sramek et al. do not disclose the step of supplying the anticoagulant fluid at a location adjacent the distal end of the cannula (see Sramek et al., par 0046, at lines 20-24). However, Shapira discloses a minimally invasive method including the step of supplying the anticoagulant fluid at a location

adjacent the distal end of the cannula (see fig. 2). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Sramek et al. with a method step similar to that of Shapira in order to prevent the sample from drying and occluding the aspiration tube/lumen and to provide a fluid aspirate for easier processing (see Shapira, column 8/lines 51-56; see Sramek et al., par 0046, at lines 20-24).

12. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sramek et al. ('373) in view of Shapira (US Patent No. 5,913,859) further in view of Kensey (US Patent No. 4,744,364).

Sramek et al. as modified by Shapira disclose a method, as described above, that teaches all the limitations of the claim except Sramek et al. as modified by Shapira do not disclose the step of providing and inserting a sheath percutaneously co-axially about a portion of the apparatus. However, Kensey discloses a method wherein a sheath 26 is provided co-axially about a portion of an apparatus 20 and inserted percutaneously (see fig. 1). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Sramek et al. as modified by Shapira with a method step similar to that of Kinsey since it is widely known to use introducer sheaths to hold percutaneous puncture sites.

13. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sramek et al. ('373) in view of Shapira (US Patent No. 5,913,859) further in view of Perez et al. ('448).

Sramek et al. as modified by Shapira disclose a method, as described above, that teaches all the limitations of the claim except Sramek et al. as modified by Shapira do not disclose the step of aspirating the sample through a plurality of circumferentially spaced radially oriented apertures at the distal end of the cannula. However, Perez et al. discloses a method wherein a fluid is irrigated through a plurality of circumferentially spaced radially oriented apertures 13 at the distal end of a cannula 11 (see fig. 6). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Sramek et al. as modified by Shapira with a method step similar to that of Perez et al. in order to guide the flow of liquid or sample inside (i.e. for collection) or outside (i.e. for irrigation) (see Perez et al., column 3/lines 47-54).

14. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shapira ('859) in view of Huitema et al. ('237) further in view of Perez et al. ('448).

Shapira as modified by Huitema et al. discloses a minimally invasive method, as described above, that teaches all the limitations of the claim except Shapira as modified by Huitema et al. does not disclose a step of aspirating the sample through a plurality of circumferentially spaced radially oriented apertures at the distal end of the cannula. However, Perez et al. discloses a method wherein a fluid is irrigated through a plurality of circumferentially spaced radially oriented apertures 13 at the distal end of a cannula 11 (see fig. 6). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Sramek et al. as modified by Shapira with a method step similar to that of Perez et al. in order to guide

the flow of liquid or sample inside (i.e. for collection) or outside (i.e. for irrigation) (see Perez et al., column 3/lines 47-54).

15. Claims 57, 59 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perez et al. (US Patent No. 6,132,448) in view of Miller et al. (US Patent No. 5,575,293).

In regards to claims 57 and 63, Perez et al. disclose an apparatus, as described above, that teaches all the limitations of the claim except Perez et al. does not teach a control means for controlling said rotation, suction and irrigation means. However, Miller et al. disclose an apparatus 202 wherein said means 208 capable of controllably supplying irrigation fluid is operatively coupled to control means 250 capable of controlling said means for applying suction in order that irrigation fluid flow and suction can be oscillated so as not to coincide (see fig. 5). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an apparatus similar to that of Perez et al. with a controller similar to that of Miller et al. in order to automatically carry out tissue collection operations (i.e. through a programmable sequence).

In regards to claim 59, Perez et al. disclose an apparatus, as described above, that teaches all the limitations of the claim except Perez et al. does not teach a collection chamber. However, Miller et al. disclose a minimally invasive apparatus 202 further comprising a collection chamber (10, 110) in fluid communication with said internal passage capable of receiving and collecting the harvested bone marrow cells, blood, and bone fragments (see fig. 5). It would have been obvious to one of ordinary

skill in the art at the time Applicant's invention was made to provide an apparatus similar to that of Perez et al. with a collection chamber similar to that of Miller et al. in order to collection the severed tissue (see Miller et al., fig. 3).

Response to Arguments

16. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Max Hindenburg

MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

RTT